UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,797	08/19/2003	Richard G. Langlois	IL-11052	7465

24981 7590 02/23/2009

Lawrence Livermore National Security, LLC
LAWRENCE LIVERMORE NATIONAL LABORATORY
PO BOX 808, L-703
LIVERMORE, CA 94551-0808

EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
02/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/643,797
Filing Date: August 19, 2003
Appellant(s): LANGLOIS ET AL.

Eddie Scott
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 24, 2008 appealing from the Office action mailed November 14, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2002/0187470	Casey et al.	12-2002
6468330	Irving et al.	10/2002
6576459	Miles et al.	6-2003

2003/0032172	Colston et al.	2-2003
6,897,031	Fisher et al.	5-2005

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5, 12, 15, 16, 27, 32, 33, 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irving et al. [US 6,468,330] in view of Casey et al. [US 2002/0187470].

With respect to claim 1, Irving et al. teach a particle separation assembly for separating particles from a gas and collecting the particles within a liquid (column 3, lines 30-35), which would therefore be capable of separating selected potential bioagent particles from air, such as toxic microorganisms (abstract). Irving et al. further teach that the particle separation assembly comprises a plurality of cyclone separation chambers and a liquid passage conduit connectable to the pump for delivering liquid to each cyclone separation chamber such that particles would be collected with the liquid by washing down the inner wall of each cyclone chambers and trapping the particles within the liquid (column 3, lines 40-58). This system would thereby constitute a wetted wall cyclone collector that would be capable of concentrating potential bioagent particles in a liquid. Irving et al. further teaches that the assembly may be used for a wide range of applications and can be integrated with a number of different biosensor or detector technologies (abstract, column 4, lines 5-20). Irving et al. do not specify that the biosensor or detector comprises a device for adding optically encoded microbeads imbedded with precise ratios of red and orange fluorescent dyes, resulting in an array of beads having unique spectral addresses and

coated with capture antibodies specific for a given antigen and potential bioagent particles that includes a flow cytometer with a laser unit for individually interrogating the microbeads.

Casey et al., however, teach a detection system for detecting microbial contamination involving lysing a cell suspension and extracting the DNA (para. 0314) and binding the DNA to probes comprising hapten recognizing intermediaries such as antibodies (para. 0065). The probes may be immobilized on optically encoded microparticles comprising polystyrene microspheres with two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256-0257). Casey et al. further teach that this would allow for multiplexed assays involving multiple analytes (para. 0256), thus allowing for analysis of a greater number of analytes simultaneously. Casey et al. also teach a flow cytometer comprising a laser unit capable of detecting and discerning selected tags on an individual bead (para. 0022, 0269) for performing the multiplexed assays (para. 0269).

Therefore, it would have been obvious to one of ordinary skill art at the time of the invention to for the detector integrated to the particle separation assembly of Irving et al. to comprise a flow cytometer and a unit for adding optically encoded microspheres comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence ., as suggested by Casey et al., in order allow for a greater number of labels, which would allow for multiplexed assays that would allow for a greater number of analytes to be detected.

With respect to the preamble, the recitation autonomous monitoring apparatus has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble

for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to automate the system of Irving et al. and Casey et al., since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

With respect to claim 2, Irving et al. also describes the particle separation assembly as an aerosol collector (column 3, lines 55-58).

With respect to claims 3-4, Irving et al. teach that the gas may comprise large interfering particles and small particles, and that the particle separator and collection assembly is capable of removing the large interfering particles greater than 50 μm, and capture and concentrate particles less than 50 μm, which would include bioagent particles (column 1, lines 16-33).

With respect to claim 5, the cyclone collector taught by Irving comprises a two stage system of concentric components to remove large interfering particles and retain small particles for collection and analysis, where a large outer cyclone is used to separate particles and an inner bank of mini-cyclones is used to capture and concentrate particles, wherein particle-laden gas is pulled through the at least one cyclone chambers by a blower so that the particles are separated from the gas by centrifugal force and collected by the liquid supplied to the at least one cyclone chambers (column 3, lines 5-30).

With respect to claim 12, the detection system contains a lysing mechanism (para. 0314) which would be capable of lysing bioagent particles containing spores.

With respect to claims 15, 16, the cyclone collector taught by Irving may include a fluid collection port as well as a secondary injection port (column 10, lines 28-45), which would be capable of sequential injection as well as flow injection, and would therefore read upon the claims.

With respect to claim 27, Casey et al. teach polystyrene microspheres, as discussed above (para. 0257).

With respect to claims 32, Casey et al. teach PCR detectors for multiplex detection of analytes (see 0014, 0269).

With respect to claim 33, 35-37, Casey et al. also teach a flow cytometer comprising a laser unit capable of detecting and discerning selected tags on an individual microsphere (para. 0022, 0269), wherein the detection means involves PCR amplification (para. 0014), and may be multiplexed (para. 0269) and in real-time (para. 0162-0166).

With respect to claims 38, 39, Casey et al. teach means for injecting a sample and adding PCR reagents, as well as for transporting to and from a PCR reactor in the form of pipettes (para. 0319), means for mixing the sample and reagent (para. 0317-319), and means for detecting the PCR amplified product involving gel electrophoresis (para. 00320). Irving et al. also disclose means for cleaning the conduits such as the inlets and cyclone separators of the particle separation assembly (column 12, lines 35-41), which would decontaminate and condition the conduits.

With respect to claim 40, Casey et al. teach that the microspheres may be suspended and resuspended (para. 0259).

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Irving et al. [US 6,468,330] in view of Casey et al. [US 2002/0187470] as applied to claim 1 above, and further in view of Colston, Jr. et al. [US 2003/0032172].

With respect to claim 19, Irving et al. and Casey et al. teach the invention as discussed above, but fail to teach a super serpentine reactor to help prepare the sample.

Colston, Jr. et al., however, teach that mixers such as super serpentine reactors may be used to combine the sample and the PCR reagents (para. 0043). Therefore, one of ordinary skill in the art at the time of the invention, when presented with these two references, would have found it obvious to utilize the super serpentine reactor of Colston, Jr. et al. to perform the mixing of the reagents and PCR sample during the PCR preparation stage in the invention of Irving et al. and Casey et al., in order to ensure a proper mixing of the PCR sample with the reagents so that accurate PCR amplification and analysis may be performed.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Irving et al. [US 6,468,330] in view of Casey et al. [US 2002/0187470] as applied to claim 1 above, and further in view of Fisher et al. [US 6,897,031].

With respect to claim 29, Irving and Casey et al. teach the invention as discussed above. More specifically, Casey et al. teach a flow cytometer for used in a FACS-based method (para. 0022), but fail to teach that the flow cytometer comprises a red laser and a green laser.

Fisher et al., however, teaches a FACS machine for use in flow cytometry analysis (column 4, lines 47-55, 59-68), wherein multiple different lasers may each be used such that different measurements may be determined simultaneously from an individual particle (column

5, lines 48-65), wherein the lasers may be used to excite orange, red, green, and blue dyes (column 7, lines 65—column 8, lines 1-11), which would involve red and green lasers.

Therefore, one of ordinary skill in the art at the time of the invention would have found it obvious to have had multiple lasers, including a green laser and a red laser in the flow cytometer of Casey et al., in order to provide more flexibility in detecting multiple different parameters of the microspheres of Casey et al. simultaneously, allowing for more complex analysis to occur in a more rapid manner.

Claims 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irving et al. [US 6,468,330] in view of Casey et al. [US 2002/0187470] as applied to claim 1 above, and further in view of Miles et al. [US 6,576,459].

With respect to claims 31, 34, Irving et al. and Casey et al. teach the invention as discussed above, but fail to teach liquid based multiplexed immunoassay detectors.

Miles et al., however, teach both immunoassay and PCR detectors (see 46, 77 of the figure). More specifically, Miles et al teach a flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), which would also be capable of functioning as a liquid array based multiplex immunoassay or PCR detector for analyzing infection agents and spores (column 2, lines 50-65), and which would be capable of analyzing optically encoded microbeads, such as those of Casey et al. (column 3, lines 25-41). Miles et al. also teach the use of Taqman assays (column 4, lines 60-65) which are quantitative PCR assays and which would require a PCR detector, and that the fluorescent signal is detected in real-time (column 4, lines 64-65).

Therefore, Miles et al. show that multiplexed immunoassay detectors and multiplexed PCR detectors are equivalent structures known in the art. Therefore, because these two types of detectors were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute a multiplexed immunoassay detector for a PCR detector

(10) Response to Argument

Applicant's arguments filed November 24, 2008 have been fully considered but they are not persuasive.

With respect to applicant's argument regarding the preamble on p. 12, the recitation "autonomous monitoring apparatus" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Since applicant has not recited any structural features necessary for the autonomous monitoring that would distinguish the claim for the prior art, the claims would read on the prior art. Furthermore, as discussed in the rejection filed November 14, 2008, it would have been obvious to one having ordinary skill in the art at the time the invention was made to automate the system of Irving et al. and Casey et al., since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

With respect to applicant's argument on p. 13 that Irving and Casey do not teach a collector for gathering air being monitored, said collector separating selected potential bioagent particles from said air, the Office notes, as discussed in the action filed November 14, 2008, Irving et al. teach a particle separation assembly for separating particles from a gas and collecting the particles within a liquid (column 3, lines 30-35), which would be capable of gathering gases such as air, and separating potential bioagent particles from said air (column 1, lines 16-33). It is also noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, since the structure of Irving et al. is capable of performing the intended use, it meets the claim limitation.

With respect to applicant's argument on p. 13, 14 that the prior art fails to teach a wetted wall sample preparer connected to the collector and a cyclone collector unit for adding optically encoded microbeads, the Office notes that Irving et al. further teach that the particle separation assembly comprises a plurality of cyclone separation chambers and a liquid passage conduit connectable to the pump for delivering liquid to each cyclone separation chamber such that particles would be collected with the liquid by washing down the inner wall of each cyclone chambers and trapping the particles within the liquid (column 3, lines 40-58). This system would thereby constitute a wetted wall cyclone collector that would be capable of concentrating potential bioagent particles in a liquid. Casey et al. further teach a detection system for detecting microbial contamination involving lysing a cell suspension and extracting the DNA (para. 0314) and binding the DNA to probes comprising hapten recognizing intermediaries such as antibodies

(para. 0065). The probes may be immobilized on optically encoded microparticles comprising polystyrene microspheres with two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256-0257). Casey et al. further teach that this would allow for multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256). Casey et al. also teach a flow cytometer comprising a laser unit capable of detecting and discerning selected tags on an individual bead (para. 0022, 0269) for performing the multiplexed assays (para. 0269).

With respect to applicant's argument on p. 14, that the prior art fails to teach a detector connected to the preparer, the Office notes that Irving et al. further teaches that the assembly may be used for a wide range of applications and can be integrated with a number of different biosensor or detector technologies (abstract, column 4, lines 5-20).

With respect to applicant's arguments on p. 14-15 that the prior art fails to teach a flow cytometer and laser unit, the Office notes that Casey et al. also teach a flow cytometer comprising a laser unit capable of detecting and discerning selected tags on an individual bead (para. 0022, 0269) for performing the multiplexed assays (para. 0269). In addition, Casey et al. teach a detection system such as the flow cytometer for detecting microbial contamination involving lysing a cell suspension and extracting the DNA (para. 0314) and binding the DNA to probes comprising hapten recognizing intermediaries such as antibodies (para. 0065). The probes may be immobilized on optically encoded microparticles comprising polystyrene microspheres with two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256-0257). Casey et al. further teach that this would allow for multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256).

With respect to applicant's argument on p. 15, 16, that there is no reasonable expectation of success, the Office notes that the Irving reference disclose that the system may be connected to detection systems for detecting microorganisms (see abstract), while Casey et al. teach detection systems that may comprise flow cytometers and lasers, as discussed above. Therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references.

The Office also notes that applicant's do not appear to be arguing that there is no reasonable expectation of success but rather appear to be arguing that the Irving and Casey references to not mention "monitoring", which would be an intended use function. However, since the claims are directed toward an apparatus claim and not toward a method, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Furthermore, the sensor of Irving is a monitoring system that can send out a warning if toxic microorganisms are present.

In response to applicant's argument on p. 16-17 that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.

1992). In this case, Casey et al. teach that this would allow for multiplexed assays involving multiple analytes, such as multiplexed genotyping of SNPs, possible (para. 0256), thus allowing for analysis of a greater number of analytes.

In particular, Casey et al. teach a detection system for detecting microbial contamination involving lysing a cell suspension and extracting the DNA (para. 0314) and binding the DNA to probes comprising hapten recognizing intermediaries such as antibodies (para. 0065). The probes may be immobilized on optically encoded microparticles comprising polystyrene microspheres with two fluorescent dyes incorporated in different ratios of red and orange fluorescence (para. 0256-0257). Casey et al. further teach that this would allow for multiplexed assays involving multiple analytes (para. 0256), thus allowing for analysis of a greater number of analytes simultaneously. Casey et al. also teach a flow cytometer comprising a laser unit capable of detecting and discerning selected tags on an individual bead (para. 0022, 0269) for performing the multiplexed assays (para. 0269).

Therefore, it would have been obvious to one of ordinary skill art at the time of the invention to for the detector integrated to the particle separation assembly of Irving et al. to comprise a flow cytometer and a unit for adding optically encoded microspheres comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence ., as suggested by Casey et al., in order allow for a greater number of labels, which would allow for multiplexed assays that would allow for a greater number of analytes to be detected.

Applicant's arguments on p. 18-22, with respect to the autonomous monitoring apparatus appear to be have already been addressed above, with respect to Irving and Casey.

With respect to applicant's argument that there is no reasonable expectation of success, the Office again notes that applicants have not shown why the combination of Irving and Casey would not work together. The Office notes that the Irving reference disclose that the system may be connected to detection systems for detecting microorganisms (see abstract), while Casey et al. teach detection systems that may comprise flow cytometers and lasers, as discussed above. Therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references.

With respect to applicant's arguments that there is no reason for combining the references, the Office notes, as discussed above, that Colston, Jr. et al. teach that mixers such as super serpentine reactors may be used to combine the sample and the PCR reagents (para. 0043). Therefore, one of ordinary skill in the art at the time of the invention, when presented with these two references, would have found it obvious to utilize the super serpentine reactor of Colston, Jr. et al. to perform the mixing of the reagents and PCR sample during the PCR preparation stage in the invention of Irving et al. and Casey et al., in order to ensure a proper mixing of the PCR sample with the reagents so that accurate PCR amplification and analysis may be performed.

Applicant's arguments on p. 22-26, with respect to the autonomous monitoring apparatus appear to be have already been addressed above, with respect to Irving and Casey.

With respect to applicant's argument that there is no reasonable expectation of success, the Office again notes that applicants have not shown why the combination of Irving and Casey would not work together. The Office notes that the Irving reference disclose that the system may be connected to detection systems for detecting microorganisms (see abstract), while Casey et al. teach detection systems that may comprise flow cytometers and lasers, as discussed above.

Therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references.

With respect to applicant's argument on p. 26 that there is no reason to combine the references, the Office notes that as discussed above, Fisher et al. teaches a FACS machine for use in flow cytometry analysis (column 4, lines 47-55, 59-68), wherein multiple different lasers may each be used such that different measurements may be determined simultaneously from an individual particle (column 5, lines 48-65), wherein the lasers may be used to excite orange, red, green, and blue dyes (column 7, lines 65—column 8, lines 1-11), which would involve red and green lasers. Therefore, one of ordinary skill in the art at the time of the invention would have found it obvious to have had multiple lasers, including a green laser and a red laser in the flow cytometer of Casey et al., in order to provide more flexibility in detecting multiple different parameters of the microspheres of Casey et al. simultaneously, allowing for more complex analysis to occur in a more rapid manner.

Applicant's arguments on p. 27-32 with respect to the autonomous monitoring apparatus appear to be have already been addressed above, with respect to Irving and Casey.

With respect to applicant's argument that there is no reasonable expectation of success, the Office again notes that applicants have not shown why the combination of Irving and Casey would not work together. The Office notes that the Irving reference disclose that the system may be connected to detection systems for detecting microorganisms (see abstract), while Casey et al. teach detection systems that may comprise flow cytometers and lasers, as discussed above.

Therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references.

With respect to applicant's argument on p. 32 that there is no reason to combine the references, the Office notes that as discussed above, Miles et al. teach both immunoassay and PCR detectors (see 46, 77 of the figure). More specifically, Miles et al teach a flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), which would also be capable of functioning as a liquid array based multiplex immunoassay or PCR detector for analyzing infection agents and spores (column 2, lines 50-65), and which would be capable of analyzing optically encoded microbeads, such as those of Casey et al. (column 3, lines 25-41). Miles et al. also teach the use of Taqman assays (column 4, lines 60-65) which are quantitative PCR assays and which would require a PCR detector, and that the fluorescent signal is detected in real-time (column 4, lines 64-65).Therefore, Miles et al. show that multiplexed immunoassay detectors and multiplexed PCR detectors are equivalent structures known in the art. Therefore, because these two types of detectors were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute a multiplexed immunoassay detector for a PCR detector.

With respect to applicant's argument on p. 33, 34, that applicant's invention provides unexpected results, the Office could not find any evidence or data that supports applicant's assertion that applicant's invention provides unexpected results. The Office notes that any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the

difference is really unexpected. *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (differences in sedative and anticholinergic effects between prior art and claimed antidepressants were not unexpected). In *In re Waymouth*, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974), the court held that unexpected results for a claimed range as compared with the range disclosed in the prior art had been shown by a demonstration of "a marked improvement, over the results achieved under other ratios, as to be classified as a difference in kind, rather than one of degree." Compare *In re Wagner*, 371 F.2d 877, 884, 152 USPQ 552, 560 (CCPA 1967) (differences in properties cannot be disregarded on the ground they are differences in degree rather than in kind); *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) ("we generally consider a discussion of results in terms of 'differences in degree' as compared to 'differences in kind' . . . to have very little meaning in a relevant legal sense").

With respect to applicant's argument on p. 34-35 that applicant's invention has been licensed and has obtained commercial success and has obtained recognition by peers and praise by others, the Office notes that objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. *In re Tiffin*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971) (evidence showing commercial success of thermoplastic foam "cups" used in vending machines was not commensurate in scope with claims directed to thermoplastic foam "containers" broadly). In order to be commensurate in scope with the claims, the commercial success must be due to claimed features, and not due to unclaimed features. *Joy Technologies Inc. v. Manbeck*, 751 F. Supp. 225, 229, 17 USPQ2d 1257, 1260 (D.D.C. 1990), *aff'd*, 959 F.2d 226, 228, 22 USPQ2d 1153, 1156 (Fed. Cir. 1992). An affidavit or declaration attributing commercial success to a product or process "constructed according to the disclosure and claims

of [the] patent application" or other equivalent language does not establish a nexus between the claimed invention and the commercial success because there is no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever commercial success may have occurred is attributable to the product or process defined by the claims. *Ex parte Standish*, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & Inter. 1988). Since applicant has not demonstrated that the commercial success is due to the subjected recited in the claims, applicant's arguments are not found persuasive.

With respect to applicant's arguments on p. 35-36 that the invention fulfills a long felt need, the Office notes that establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967) ("Since the alleged problem in this case was first recognized by appellants, and others apparently have not yet become aware of its existence, it goes without saying that there could not possibly be any evidence of either a long felt need in the . . . art for a solution to a problem of dubious existence or failure of others skilled in the art who unsuccessfully attempted to solve a problem of which they were not aware."); *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.,* 707 F.2d 1376, 217 USPQ 1281 (Fed. Cir. 1983) (Although the claimed invention achieved the desirable result of reducing inventories, there was no evidence of any prior unsuccessful attempts to do so.). Second, the long-felt need must not have been satisfied by another before the invention by applicant. *Newell Companies v. Kenney Mfg. Co.*, 864 F.2d 757, 768, 9 USPQ2d

1417, 1426 (Fed. Cir. 1988) (Although at one time there was a long-felt need for a "do-it-yourself" window shade material which was adjustable without the use of tools, a prior art product fulfilled the need by using a scored plastic material which could be torn. "[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved".) Third, the invention must in fact satisfy the long-felt need. *In re Cavanagh*, 436 F.2d 491, 168 USPQ 466 (CCPA 1971). Therefore, since applicant has not shown any evidence of prior unsuccessful attempts of others to achieve the long felt need, applicant's arguments are not found persuasive.

It is also noted that long-felt need is analyzed as of the date the problem is identified and articulated, and there is evidence of efforts to solve that problem, not as of the date of the most pertinent prior art references. *Texas Instruments Inc. v. Int'l Trade Comm'n*, 988 F.2d 1165, 1179, 26 USPQ2d 1018, 1029 (Fed. Cir. 1993). And that the failure to solve a long-felt need may be due to factors such as lack of interest or lack of appreciation of an invention's potential or marketability rather than want of technical know-how. *Scully Signal Co. v. Electronics Corp. of America*, 570 F.2d 355, 196 USPQ 657 (1st. Cir. 1977).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Nelson Yang/

Primary Examiner, Art Unit 1641

Conferees:

Mark Shibuya

/Mark L. Shibuya/

Supervisory Patent Examiner, Art Unit 1641

Robert Mondesi

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645